(b) if so, by when the notification will be issued;

(c) whether it is also a fact that all new manufacturers seeking permission for four Drugs Fixed Dose Combination will have to do the bio-equivalence;

(d) if so, the names of testing labs which are authorized to do this bio-equivalence; and

(e) whether it is also a fact that these B.E. reports will have to be submitted to DCGI for getting approval?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) and (b) The matter of Fixed Dose Combination of four Anti-T.B. drugs *viz.* Rifampicin+Isoniazid+ Pyrazinamide+Ethhambutol was discussed and deliberated in Drug Technical Advisory Board (DTAB) meeting and principally DTAB agreed for introduction of FDC of four Anti-T.B. drugs, as per formula recommended by the WHO and the formula included in WHO Model List of Essential Drugs.

(c) to (e) The matter regarding requirement of bio-equivalence study for new permission to manufacture Fixed Dose Combination of four Anti-T.B. drugs are under examination.

Bio-equivalence studies are mainly required for oral dosage forms of new drugs. There are number of Bio-Availability/Bio-Equivalence study centres (BA/BE) in the country and no specific authorization is required. Based on the expertise and infrastructure available with the centres, the study reports are considered for approval of new drug.

Ethical guidelines for Bio-Medical Research on human beings

2701. SHRI RAMACHANDRA KHUNTIA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that since the ethical guidelines for bio-medical research on human subjects are not binding, it exposes human beings to potential exploitation;

(b) if so, whether Government propose to bring a legislation in this

regard in order to ensure that all the guidelines are being strictly followed by every one;

(c) if so, the details thereof; and

(d) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (d) The Ethical Guidelines for Bio-Medical Research on Human Subjects framed by the Indian Council of Medical Research (ICMR) under the Chairmanship of Justice M.N.V. Venkatachaliah were circulated among Bio-Medical Research Institutions in the country for being followed in letter and spirit. Government also proposes to bring in a legislation to ensure that these guidelines are legally enforceable.

Functioning of Electropathy Institutions

2702. SHRI BHAGATRAM MANHAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the High Court of Delhi in its judgement on 18th November, 1998 in case No. 4015/96 has directed the Central/ State Governments to formulate the functioning of Electropathy Institutions on the lines of Sections 17,18,19 and 19 (A) of Medical Council Act, 1956 in order to streamline functioning of the system;

(b) if so, the action Government have taken in the matter;

(c) whether any instructions have also been issued to State Governments in this regard; and

(d) if so, the response of the State Governments thereto?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (d) Hon'ble High Court of Delhi in its order dated 18.11.98 in the case No. 4015/96 has directed the Central and State Governments to consider making legislation prescribing grant of licences to the institutes conducting courses in Electropathy and other alternative systems of medicine, minimum standard of education on functioning of such institutes on the lines set out in Sec. 17, 18, 19 & 19A of Medical Council Act, 1956 minimum qualification for getting admission in such institutes, conditions entitling these institutes to issue diploma and certificates etc. In pursuance of the said order and also to examine